

WE CLAIM:

5                   1.    A medical diagnostic device for measuring an  
                    analyte concentration of an electrically conductive  
                    biological fluid, comprising a multilayer structure  
                    having a first layer and a second layer sandwiching an  
                    intermediate layer,

10                   a)    the first and second layers each  
                    comprising an insulating sheet, having a conductive  
                    surface adjoining the intermediate layer,

15                   b)    the intermediate layer being an insulating  
                    layer with a cutout, having a first end and a  
                    second end, which, together with the first and  
                    second layers, defines                   a flow  
                    channel to permit the sample to flow from the  
                    first end to the second end,

                    c)    the flow channel comprising

20                   (i)   a dry reagent on the conductive surface of one  
                    of the layers for reacting with the sample to yield a  
                    change in an electrical parameter that can be related to  
                    the analyte concentration of the fluid and

                    (ii) an electrochemical cell, within which  
                    the electrical parameter is measured,

25                   d)    the conductive surface of one of the  
                    layers having a first insulating pattern scored  
                    into its conductive surface to divide the  
                    second layer into two regions, insulated from  
                    each other, whereby sample that flows across

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the pattern provides a conductive path from the first end to the second end.

2. The device of claim 1, in which the first end of the cutout is at a first edge of the intermediate layer and the second end is at a second edge of the intermediate layer, opposite the first edge.

3. The device of claim 1, in which the dry reagent is on the conductive surface of the first layer and the insulating pattern is scored into the conductive surface of the second layer.

4. The device of claim 1, in which sample that enters the flow channel at the first end flows through the electrochemical cell, before it reaches the first insulating pattern.

5. The device of claim 1, in which the biological fluid is blood and the analyte being measured is glucose.

6. The device of claim 1, in which the first and second layers each comprise metallized thermoplastic sheets.

7. The device of claim 1, in which the intermediate layer comprises a thermoplastic sheet having adhesive on both surfaces for adhering to the first and second layers.

8. The device of claim 1, in which the reagent on the conductive surface comprises a buffer, a mediator, and an enzyme.

9. The device of claim 1, in which the flow channel is a capillary channel and the insulating pattern

scored into the conductive surface has at least one serration within the flow channel.

10. The device of claim 9, in which the insulating pattern has at least one serration within the flow channel pointing toward each end of the channel.

11. The device of claim 1, further comprising a second insulating pattern scored into the conductive surface of the scored layer between the first end and the first insulating pattern to divide the scored layer into three regions, insulated from each other.

12. The device of claim 11, in which sample that enters the flow channel at the first end reaches the second insulating pattern before it flows through the electrochemical cell.

13. The device of claim 1, further comprising electrical circuit means for detecting the flow of fluid through the flow channel.

14. A method for preparing an electrically-conductive pattern comprising passing a web of a conductive-coated flexible insulator between a cutting die and anvil, in which the cutting die has a cutting element that is raised a height greater than the thickness of the conductive coating for scoring through preselected portions of the conductive coating.

15. The method of claim 14, in which the cutting die and anvil are rollers.

16. The method of claim 14, in which the conductive coating has a thickness in the range from about 5 to

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about 100 nm and the cutting element is raised about one thousand times the coating thickness.

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